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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,941	04/16/2007	Hiroshi Kawashima	47635-0024-00-US (226682)	7395

55694 7590 06/04/2010

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EXAMINER	
SHOMER, ISAAC	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
06/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPDocket@dbr.com
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Office Action Summary	Application No.	Applicant(s)	
	10/581,941	KAWASHIMA ET AL.	
	Examiner	Art Unit	
	ISAAC SHOMER	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,8-13,16-23 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,8-13,16-23 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9 December 2009, 22 March 2010, 2 April 2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 30 March 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement filed on 9 December 2009 (on the same day as the mailing of the first action) fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement filed on 2 April 2010 lists the same references as that filed on 9 December 2009 but further includes the statement as specified in 37 CFR 1.97(e). As the required reference had already been provided on 9 December 2009, they do not need to be provided again. As such, this information disclosure statement is considered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 5, 8-13, 16-18, 21, 22, and 26-28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponroy (US patent 5,591,479).

Ponroy teaches a composition comprising phospholipids and fatty acids to be used as a nutritional supplement for premature babies, as of Ponroy, abstract. Suggested for inclusion in said composition are glycerides[1] (i.e. fatty acids bound to the glycerol molecule), wherein said glycerides include about 8.5% arachidonic acid as a percentage of the total fatty acids, as of Ponroy, column 2 lines 39-41 and 45-46. In a separate embodiment, Ponroy suggests that the composition contain from 1% to 20% of cerebral phospholipids, as of Ponroy, column 4 lines 1-5, wherein said phospholipids include phosphatidylserine, as of Ponroy, column 2 lines 26-32. Said formulation is useful for food supplementation for malnourished patients, as of Ponroy, column 1 lines 4-10, specifically premature babies, as of Ponroy, column 2 lines 53-56. Liposomes and emulsions (e.g. dispersions) are taught by Ponroy, column 3 lines 51-56. DHA is also taught to be about 9%, as of Ponroy, column 2 lines 51-52.

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables specifically a composition comprising arachidonic acid, and phospholipids including phosphtidylserine, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007) (quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients specifically a composition comprising arachidonic acid, and phospholipids including phosphtidylserine from within a prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

Given Ponroy's disclosure of 1-20% phospholipids and about 8.5% arachidonic acid, this appears to result in a ratio of arachidonic acid to phospholipids that ranges

[1] Glycerides may also be interpreted as fatty acid alcohol esters, as the fatty acid chain appears to be

from 8.5 to 0.425, thereby overlapping with the requirements that the ratio be “not less than 0.5” as of claim 1 and "not less than 2” as of claim 26. While the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

The phospholipid mixture taught by Ponroy appears to have been derived from pigs, as of Ponroy, column 2 lines 23-25. However, the patentability of a product does not depends from its method of production, and as such, any claims that require that the phospholipids (specifically phosphatidylcholine and phosphatidylserine) be derived from plants do not differentiate the claim from the prior art as both of these phospholipids are taught by Ponroy. See MPEP 2113.

Claims 1, 4, 5, 8-13, 16-18, 21-23, and 26-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Ponroy (US patent 5,591,479) as applied to claims 1, 4, 5, 8-13, 16-18, 21, 22, and 26-30 above, and further in view of “Ultimate Gingko” (http://www.edietstar.com/fact_sheet/ultimate_ginkgo.pdf- 12 March 2003, as of Internet Archive).

Ponroy teaches a composition comprising arachidonic acid, DHA, and phospholipids including phosphatidylserine. Said composition appears to be useful in promoting the growth of cereberal functions of premature babies, as of Ponroy, column 1 lines 43-47.

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esterifying the alcohol glycerol.

Ponroy does not teach a composition in the form of a tablet (as premature babies would not be reasonably expected to swallow a tablet).

Ultimate Gingko teaches a composition comprising DHA[2], phosphatidyserine, other phospholipids and excipients, as of Ultimate Gingko, first page. Said composition is in the form of a tablet, and appears to have been useful for improving and maintaining brain activity by combating problems of old age, as of Ultimate Gingko, third paragraph. The amount of DHA as a proportion of all of the fatty acids appears to be at least 10/(10+10+23) = 23%, wherein here is 10 mg DHA, 10 mg phosphatidylserine, and 23 mg of bioabsorption complex, which is assumed to be lecithin it its entirety.

It would have been prima facie obvious for one of ordinary skill in the art to have modified the nutriment of Ponroy to have been in the form of a tablet and to have increased the amount of DHA present. This is because a composition comprising phospholipids and DHA is useful not only for improving brain function in infants, as of Ponroy, but also would have predictably improving brain function in older adults with a reasonable expectation of success, as of Ultimate Gingko. The skilled artisan would have been motivated to have formulated said composition into a tablet as this is a dosage form predictably suitable for older adults with a reasonable expectation of success. Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07.

[2] DHA appears to be the only fatty acid present, thereby reading on claim 30.

As DHA appears to be the only identified long chain polyunsaturated fatty acid (LCPUFA), as of Ultimate Gingko, it appears that DHA comprises 100% of the total content of long chain polyunsaturated fatty acids in Ultimate Gingko. As DHA comprises about 9% of the total LCPUFA in Ponroy, it appears that the percentage of DHA with respect to the total LCPUFA content ranges from 9% to 100%, overlapping with the claimed range of not less than 11%. While the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612